K001361

JUL 1 9 2000

# 510k Summary

**Device Information:**

A) Device Proprietary name: Jilco Traction-Flexion Chair

B) Common name: Jilco Chair

C) Classification name: Equipment, Traction, and Powered

D) Class and Reference: [redacted] (21 CFR Section 89.5900)

E) Product Code: ITH

**Device Description:**

The Jilco Traction-Flexion Chair is designed to mitigate pain of a patient's lower back by position and by application of distractive forces.

The key elements are as follows:

1) The Jilco Chair is similar to a recliner chair in appearance and allows a fully clothed patient to sit down in the chair. Once the patient is in position, the operator (doctor or qualified technician) secures the patient's torso with the seat belt and patient places his/her arms over the armrest supports. The chair is then lowered to a horizontal position by a hand held controller held by the operator.
2) Once the patient is in the horizontal position the operator raises the armrest supports until the desired distraction is achieved. Minimum and maximum distraction forces are 0-150 lbs.
3) Once desired distraction is achieved the operator can then start the lower leg apparatus to initiates a gentle and slow cycling in which the legs are raised and lowered to facilitate the distraction. This provides a gentle stretching to the lumbar musculature (this is an optional feature and does not have to be used by all patients).
4) The Jilco Chair is programmed and controlled by means of a hand held control device that is directly connected to the Jilco Chair
5) Treatment parameters, i.e. tension and time are continuously monitored and shown by LCD readout on the hand held control device.
6) The patient has possession of a patient safety switch that will immediately stop all tension and moving parts when activated. This switch consists of a patient held large red emergency stop button switch. The operator can also push a stop button at any time.

7) The Jilco chair will not operate if the patient safety switch is not fully functional.
8) Treatment cannot be restarted once safety switch has been activated until the parameters are reset by the operator and re-entered into the control device.

**Intended Use**:

The Jilco Traction-Flexion Chair is designed to relieve pressure on muscular and skeletal structures that may be causing low back pain. Each treatment consists of a physician recommended treatment period on the Jilco Chair and is designed to provide intermittent, static, and cycling distraction forces to relieve pressures on musculo-skeletal structures that may be causing low back pain. It helps to relieve pain associated with degenerative discs, herniated discs, protruding discs, facet syndrome, and sciatica. The pain mitigation is accomplished by decompression of intervertebral discs and associated structures. The Jilco chair is sold only to licensed health care practitioners. It is intended to be used in the practitioner's office.

**Technological Characteristics**:

The Jilco Traction-Flexion Chair is a U.S. patented device (patent #5437609) that incorporates all the benefits of a horizontal traction table but delivers the treatment in a comfortable reclining position rather than the patient lying supine on a cold, hard table. The working principles of the Jilco Chair is the same as the legally marketed predicate device, the DRS System (K981822). It also has similar working principles of the other predicate devices: Tru-Trac Traction Table K8893448 and the VAX-D Therapeutic Table, K951622. The differences from the Jilco to the predicate device is in a) appearance, the Jilco chair looks like a recliner, b) padded cushions instead of a hard table surface, c)use of a leg raising apparatus instead of a mobile leg stool, and d) the use of underarm supports to provide traction instead of a body harness or straps. A clinical study of the Jilco Chair was performed and documented (see enclosed) and all safety concerns, and patient protections were addressed and satisfactory met.

We will further confirm that this summary contains only information that is within the main body of the 510k, with no unsubstantiated labeling, claims, raw data, trade secrets, or patient identification information.

**Summary of Safety and Effectiveness:**

The operating principles of the Jilco Traction-Flexion Chair permit application of effective distraction tensions to the lumbar spine. The important basic parameters contributing to the safety and effectiveness of the Jilco Chair include the following:

1) The control circuitry for the distraction motor is a maximum DC current of 24 volts.
2) The patient is automatically reclined from a sitting position to a supine position for treatment rather than climbing into the treatment chair.
3) The backrest reclines slowly to position the patient.
4) The armrests are padded and mobile so as not to bring irritation to the underarms or rib cage.
5) The chair is covered with naugehyde leather that facilitates easy cleaning and thereby reducing potential pathogen contamination.
6) The Jilco chair is equipped with a patient held safety, emergency stop switch that immediately halts all tensions and motions. The treatment protocol cannot continue without an operator resetting the parameters
7) There is also instantaneous release of tensions and motions when the stop button is pressed on the hand-held control panel and /or electrical current is interrupted. Again, the treatment protocol cannot continue without an operator resetting the parameters.
8) The operation of the Jilco Chair is controlled by the cognizance of a qualified operator at all times. This operator monitors the patients progress at all times and can immediately stop the tensions and motions of the Jilco chair at the first sign of patient distress.
9) All treatment parameters must be manually entered each time.
10) There is limited vertical movement of the traction apparatus.
11) There is a warning light on the control panel and on the patient safety switch that activates when the unit is turned on.
12) Most importantly, the Jilco Traction Flexion chair is not sold to the general public. It is only sold to health care practitioners who have a solid education in the care and maintenance of persons with back pain. These persons, once familiar with the operation of the Jilco chair are highly unlikely to allow any patients to be safety compromised.

The DRS System, the Tru-Trac table and the VAX-D System have all been in use in this country for more than ten years and there is no evidence of MDR report being filed by the manufacturer nor has there been any events or conditions effecting the operation of this equipment during all trials carried out by the PDS. Similarly, traction tables and traction devices have a long history of safety and effectiveness when used according to design and manufacturer's specifications. The Jilco Traction-Flexion chair falls into this same category.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUL 1 9 2000

Mr. David K. Leonard
Jilco Enterprises
11913 Armitage Drive
Grandview, Missouri 64030

Re: K001361
Trade Name: Jilco Traction-Flexion Chair
Regulatory Class: II
Product Code: ITH
Dated: undated
Received: April 28, 2000

Dear Mr. Leonard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001361

# Statement of Indications for Use

The Jilco Traction-Flexion chair is designed to provide a protocol of relief for patients that are suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the Jilco chair and is designed to provide static, intermittent, and cycling distraction to relieve pressure on muscular and skeletal structures that may be causing low back pain. Consistent use of the chair relieves pain associated with prolapsed discs, herniated discs, spinal root impingement, hypomobility, degenerative joint disease, facet syndrome, and sciatica. Treatment with the Jilco Chair mitigates the pain by static and intermittent decompression of intervertebral discs, that is , unloading due to distraction and positioning.

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001361